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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/509,487
Filing Date: September 27, 2004
Appellant(s): JUTURU ET AL.

Kathleen R. Mekjian
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 3, 2009 appealing from the Office action mailed February 4, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 2002/0086065 A1 Katz, D. 07-2002

Goodman and Gilman "The Pharmacological Basis of Therapeutics"

Pergamon Press, 8th Edition, p. 5-6, 1992.

Godsland et al "Insulin Resistance, Secretion, and Metabolism in Users of Oral Contraceptives"

Journal of Clinical Endocrinology and Metabolism, 74(1), p. 64-70, 1992.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 12 and 13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Katz (US 2002/0086065) in view of Godsland et al (Journal of Endocrinology and Metabolism, 74(1), p. 64-70, 1992).

Claims 1-7, 12 and 13 are drawn to a method of inhibiting the development of drug induced insulin resistance comprising administering chromium picolinate contemporaneously (e.g. simultaneously or within a 24 hour period) with oral contraceptive drugs or NSAIDs.

Katz teaches a method of decreasing insulin resistance comprising the oral administration of chromium picolinate at a daily dose of 1000 micrograms of chromium in a pharmaceutically acceptable carrier (paragraphs 0049, 0050 and 0071). Katz does not teach the step of identifying an individual receiving a dose of a drug (e.g. oral contraceptives) that induces insulin resistance and then administering chromium picolinate contemporaneously (e.g. simultaneously or within a 24 hour period)) with said drug.

Godsland et al teaches that oral contraceptive drugs cause insulin resistance (p. 69, left column, 1st full paragraph).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time of the instantly claimed invention to identify an individual receiving a dose of a drug that induces insulin resistance (i.e. oral contraceptives) and to then administer chromium picolinate contemporaneously (e.g. simultaneously or within a 24 hour period) with said drug to alleviate/reduce a known side effect of the drug, since oral contraceptives were known to cause insulin resistance and chromium picolinate was known to treat insulin resistance and would have been expected to treat/alleviate the oral contraceptive induced insulin resistance when coadministered, simultaneously or within a 24 hour period, with said contraceptive drug, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katz (US 2002/0086065) and Godsland et al (Journal of Endocrinology and Metabolism, 74(1), p. 64-70, 1992) as applied above, further in view of Goodman and Gilman's, The Pharmacological Basis of Therapeutics, Eight Edition, 1995.

Katz and Godsland et al as combined teach the aforementioned method but do not explicitly teach the parental administration of the chromium picolinate.

Goodman and Gilman's teaches that parenteral administration is a common route of administration without many disadvantages of oral administration including: the incapability to absorb some drugs because of their physical characteristics, emesis as a result of irritation to the gastrointestinal mucosa and destruction of some drugs by digestive enzymes or low gastric pH (p. 5, right column through p. 6).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention to administer the composition of Katz parenterally to overcome the many disadvantages of oral administration, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

(10) Response to Argument

In response to the rejection of claims 1-7, 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Katz (US 2002/0086065) in view of Godsland et al (Journal of Endocrinology and Metabolism, 74(1), p. 64-70, 1992), Appellants assert that Katz and Godsland have not provided a reasonable expectation that chromium is useful for inhibiting the development of drug-induced insulin resistance because the concept of inhibiting the onset of drug-induced insulin resistance is absent from the references, which both relate to individuals with preexisting conditions. Appellants argue that there is no reason why a composition that has been identified as being useful for the treatment of a complex disease condition, in which individuals present with numerous metabolic disturbances, i.e. polycystic ovary syndrome, would be useful for inhibiting the development of one metabolic disturbance, i.e. insulin resistance. Appellants further argue that the identification of the instantly claimed patient population, i.e. patients in which the development of insulin resistance can be inhibited, is not obvious in view of Katz and Godsland, since the references combined teach only the treatment of the insulin resistance in patients who have the condition.

In response to the rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Katz and Godsland et al, further in view of Goodman and Gilman, Appellants assert that claim 8 is not obvious in view of the instantly applied references, since Goodman and Gilman is silent with regard to insulin resistance and chromium and for the reasons discussed in connection with claims 1-7, 12 and 13.

These arguments have been carefully considered, but are not found persuasive.

Appellant's arguments appear to be centered around the assertion that Katz and Godsland et al cited do not teach the administration of chromium picolinate to the patient population as claimed and thus provides no reasonable expectation of success in inhibiting the development of drug-induced insulin resistance in the patient population who are receiving a drug that induces insulin resistance, but have not developed the condition. This is not found persuasive because it is clear from the teachings of Katz that chromium picolinate is useful for inhibiting the development of insulin resistance in patients at risk of developing the condition, e.g., inhibiting the development of insulin resistance into impaired glucose tolerance and eventually type-2 diabetes in patients, as well as those patients with pre-existing insulin resistance. Thus, the patient population of Katz et al is not limited to patients with pre-existing insulin resistance. In fact, Katz teaches that clinical studies have demonstrated that as many as 20% of patients with PCOS, i.e. polycystic ovary syndrome, do not have insulin resistance (paragraphs 0014 and 0015). The teachings of Katz indicate that patients with PCOS, who have not already developed insulin resistance, impaired glucose tolerance or type-2 diabetes, are at risk of developing insulin resistance and that this condition may eventually develop

into impaired glucose tolerance and type-2 diabetes (paragraphs 0005 and 0022). Thus, Katz makes it clear that because of the insulin sensitizing activity of chromium picolinate, the drug is useful for inhibiting the development of insulin resistance in patients at risk of developing the condition as well as inhibiting the development of insulin resistance into impaired glucose tolerance and eventually type-2 diabetes in patients with pre-existing insulin resistance (paragraph 0050). Furthermore, Katz teaches that chromium is essential for optimal insulin activity in all known insulin dependent systems, that chromium depletion is characterized by the disturbance of glucose metabolism (paragraph 0035) and that chromium supplementation in normal individuals leads to improvements in glucose tolerance and is associated with improvements of risk factors associated with diabetes (paragraph 0037), providing further motivation to one of ordinary skill in art to administer chromium in order to inhibit the development of insulin resistance in individuals at risk of developing the condition and as well as to inhibit the development of insulin resistance into impaired glucose tolerance and eventually type-2 diabetes in patients with pre-existing insulin resistance, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

In response to Appellant's arguments that there is no reason why a composition that has been identified as being useful for the treatment of a complex disease condition, in which individuals present with numerous metabolic disturbances, i.e. polycystic ovary syndrome (PCOS), would be useful for inhibiting the development of one metabolic disturbance, i.e. insulin resistance , as noted above, Katz clearly teaches

that chromium picolinate has known to have insulin sensitizing activity in normal individuals and in those with underlying medical conditions placing them at risk for developing insulin resistance and is useful in inhibiting the development of insulin resistance in patients at risk of developing the condition as well as inhibiting the development of insulin resistance into impaired glucose tolerance and eventually type-2 diabetes in patients with pre-existing insulin resistance, which provides motivation to on of ordinary skill in the art to administer the compound to a patient having insulin resistance or at risk of developing the condition. In fact, Katz teaches that the mechanism by which chromium picolinate exerts a therapeutic effect on PCOS is via insulin sensitization, which inhibits the development of the symptom of insulin resistance, which is associated with PCOS (paragraphs 0012, 0050 and 0071). Godsland et al teaches that contraceptive use is also associated with the development of insulin resistance thus providing one of ordinary skill in the art at the time of the applicant's invention was made to identify an individual receiving a dose of a drug that induces insulin resistance (i.e. oral contraceptives) and then to administer chromium picolinate contemporaneously (e.g. simultaneously or within a 24 hour period) with said drug to alleviate/reduce a known side effect of the drug, since oral contraceptives were known to cause insulin resistance and chromium picolinate was known to inhibit the development of insulin resistance, with the reasonable expectation of success in the absence of evidence to the contrary.

In response to Appellant's arguments that that claim 8 in not obvious in view of the instantly applied references, since Goodman and Gilman is silent with regard to

insulin resistance and chromium and for the reasons discussed in connection with claims 1-7, 12 and 13, it is noted that Goodman and Gilman is cited to provide motivation to parenterally administer the composition of Katz in the method rendered obvious by Katz in view of Godsland et al to one of ordinary skill in the art for the advantages suggested by Goodman and Gilman, as discussed above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Christopher R. Stone

/Christopher R Stone/

Examiner, Art Unit 1628

Conferees:

/Kay K. Kim/

Primary Patent Examiner

/Brandon J Fetterolf/

Primary Examiner, Art Unit 1642/SPE 1628(Acting)